



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Russell Mumper

Serial No.: 09/748,133

Filed: December 27, 2000

For: pH-SENSITIVE MUCOADHESIVE FILM-
FORMING GELS AND WAX-FILM
COMPOSITES SUITABLE FOR
TOPICAL AND MUCOSAL DELIVERY
OF MOLECULES

Group Art Unit: 1615

Examiner: Carlos A. Azpuru

Atty. Dkt. No.: NANO:002US

10/12/2005 HLE333 00000024 09748133
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CERTIFICATE OF MAILING 37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MS AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:	
October 6, 2005	<i>Michael C. Barrett</i>
Date	Michael C. Barrett

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

MS AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be

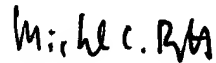
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construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

A fee as set forth in 37 C.F.R. § 1.17(p) in the amount of \$180.00 is enclosed. If an appropriate check has not been enclosed, or if it is insufficient, the Commissioner is authorized to deduct the appropriate fee from Fulbright & Jaworski Account No.: 50-1212/NANO:002US .

Applicant respectfully requests that the listed documents be made of record in the present case.

Respectfully submitted,



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Reg. No. 44,523
Attorney for Applicant

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Date: October 6, 2005



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List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

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U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	4,517,173	05/14/85	Kizawa et al.	424	16	09/25/81
	A2	4,715,369	12/29/87	Suzuki et al.	128	156	02/09/87
	A3	4,959,218	09/25/90	Eckenhoff et al.	424	473	12/28/88
	A4	5,700,478	12/23/97	Biegajski et al.	424	434	09/19/94
	A5	3,922,260	11/25/75	Peniston et al.	260	211	08/24/73

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	EP 0 435 199	07/03/91	Europe			English
	B2	WO 00 10536	03/02/00	WIPO			English
	B3	WO 00 59423	10/12/00	WIPO			English
	B4	WO 98 17251	04/30/98	WIPO			English

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Bechgaard <i>et al.</i> , "Solubilization of various benzodiazepines for intranasal administration, a pilot study," <i>Pharm Dev Tech</i> , 2:293-296, 1997.
	C2	Binnie <i>et al.</i> , "Amlexanox oral paste: a novel treatment that accelerates the healing of aphthous ulcers," <i>Compend Contin Educ Dent</i> , 18:1116-1118, 1997.
	C3	Casetta and Negretti, "Salivary immune responses after gingival immunization with tetravaccinal and bivaccinal formulations of inactivated micro-organisms," <i>Dev Biol Stand</i> , 92:317-321, 1998.
	C4	Chang, "Stability of hirudin, a thrombin-specific inhibitor," <i>J Biol Chem</i> , 266:10839-10843, 1991.
	C5	Eric and Caroline, "Influence of storage conditions on the activity of recombinant hirudin," <i>Thromb Res</i> , 61:87-89, 19991.

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List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant Russell Mumper	
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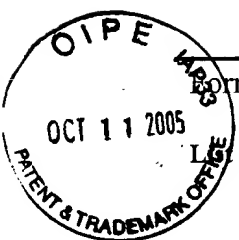
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	C6	Eriksson <i>et al.</i> , "Prevention of thromboembolism with use of recombinant hirudin. Results of a double-blind, multicenter trial comparing the efficacy of desirudin (Revasc) with that of unfractionated heparin in patients having a total hip replacement," <i>J Bone Joint Surg Am</i> , 79:326-333, 1997.
	C7	Esslinger <i>et al.</i> , "Pharmacodynamic and safety results of PEG-hirudin in healthy volunteers," <i>Throm Haemost</i> , 77:911-919, 1997.
	C8	Etchart <i>et al.</i> , "Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus hemagglutinin," <i>J Gen Virol</i> , 78:1577-1580, 1997.
	C9	Fenton <i>et al.</i> , "Thrombin inhibition by hirudin: how hirudin inhibits thrombin," <i>Haemostasis</i> , 21:27-31, 1991.
	C10	Fenton, "Thrombin interactions with hirudin," <i>Sem Thromb Hemost</i> , 15:265-268, 1989.
	C11	Garcia-Closas <i>et al.</i> , "Epidemiologic determinants of vaginal pH," <i>Am J Obstet Gynecol</i> , 180:1060-1066, 1999.
	C12	Heath <i>et al.</i> , "Mechanism of triclosan inhibition of bacterial fatty acid synthesis," <i>J Biol Chem</i> , 274:11110-11114, 1999.
	C13	Hjortkjaer <i>et al.</i> , "Single- and repeated-dose local toxicity in the nasal cavity of rabbits after intranasal administration of different glycols for formulations containing benzodiazepines," <i>J Pharm Pharmacol</i> , 51:377-383, 1999.
	C14	Jones <i>et al.</i> , "Targeting and delivery of bactericide to adsorbed oral bacteria by use of proteoliposomes," <i>Biochim Biophys Acta</i> , 1147:251-261, 1993.
	C15	Khandwala <i>et al.</i> , "5% amlexanox oral paste, a new treatment for recurrent minor aphthous ulcers: I. clinical demonstration of acceleration of healing and resolution of pain," <i>Oral Surg Oral Med Oral Pathol Oral Radiol Endod</i> , 83:222-230, 1997a.
	C16	Khandwala <i>et al.</i> , "5% amlexanox oral paste, a new treatment for recurrent minor aphthous ulcers: II. Pharmacokinetics and demonstration of clinical safety," <i>Oral Surg Oral Med Oral Pathol Oral Radiol Endod</i> , 83:231-238, 1997b.
	C17	Leopold and Eikeler, "Eudragit E as a coating material for the pH-controlled drug release in the topical treatment of inflammatory bowel disease (IBD)," <i>J Drug Targeting</i> , 6:85-94, 1998.

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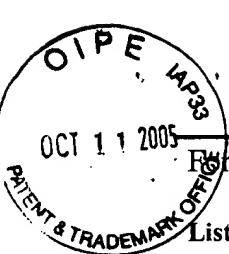
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	C18	Leung <i>et al.</i> , "Mucoadhesive dosage forms for peptide and protein drug delivery," In: <i>Peptide and Protein Drug Delivery</i> , V.H.L. Lee ed. Marcel Dekker, Inc. New York, pp. 741-767, 1991.
	C19	Liu <i>et al.</i> , "DNA vaccines: A new era in vaccinology," <i>Ann NY Acad Sci</i> , New York, NY, 772. 1995.
	C20	Loftsson <i>et al.</i> , "Effect of cyclodextrins and polymers on triclosan availability and substantivity in toothpastes in vivo," <i>J Pharm Sci</i> , 88:1254-1258, 1999.
	C21	Mandel, "Antimicrobial mouthrinses: overview and update," <i>J Am Dent Assoc</i> , 125:2S-10S, 1994.
	C22	March and Nakamura, "Evaluation of the duration of effect of a bioadhesive vaginal moisturizing gel on vaginal pH," 7 th <i>International Congress on the Menopause, Replens Symposium, Stockholm, Sweden</i> , June 20-22, 1993.
	C23	Markwardt, "Development of hirudin as an antithrombotic agent," <i>Sem THromb Hemost</i> , 15:269-282, 1989.
	C24	Markwardt, "Past, present and future of hirudin," <i>Haemostasis</i> , 21:11-26, 1991b.
	C25	Markwart, "Hirudin and derivatives as anticoagulant agents," <i>Thromb Haemost</i> , 66:141-152, 1991a.
	C26	Martin <i>et al.</i> , <i>Martin's Physical Pharmacy: Physical chemical principles in the pharmaceutical sciences</i> , Lea & Febiger, Third Ed., Philadelphia, 1983.
	C27	McGhee and Kiyono, "Mucosal immunity to vaccines: Current concepts for vaccine development and immune response analysis," In: <i>J.E. Ciarri (ed.) Genetically engineered vaccines</i> , Plenum Press, New York, NY, pp. 3-12, 1992a.
	C28	Park and Robinson, "Physico-chemical properties of water insoluble polymers important to mucin/epithelial adhesion," <i>J Cont Rel</i> , 2:47-57, 1985.
	C29	Rathbone <i>et al.</i> , In: <i>Oral J Mucosal Drug Delivery</i> , M.J. Rathbone Ed., Marcel Dekker Inc., New York, 1996.
	C30	<i>Remington's Pharmaceutical Sciences</i> , 18 th Ed., A.R. Gennard, ed. Mack Publishing Company, Easton, PA, 1990.
	C31	Riehl-Bellon <i>et al.</i> , "Purification and biochemical characterization of recombinant hirudin produced by <i>Saccharomyces cerevisiae</i> ," <i>Biochemistry</i> , 28:2941-2949, 1989.
	C32	Robinson and Torres, "C.A.T. DNA Vaccines," <i>Sem Immun</i> , 9:271-283, 1997.

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	C33	Saijo <i>et al.</i> , "Inhibition by amoxanox (AA-673) of the immunologically, leukotriene D4- or platelet-activating factor-stimulated bronchoconstriction in guinea pigs and rats," <i>Int Arch Allergy Appl Immunol</i> , 77:315-321, 1985.
	C34	Saijo <i>et al.</i> , "The antiallergic agent amoxanox suppresses SRS-A generation by inhibiting lipooxygenase," <i>Int Arch Allergy Appl Immunol</i> , 79:231-237, 1986.
	C35	Schwagmeier <i>et al.</i> , "Midazolam pharmacokinetics following intravenous and buccal administration," <i>Br J Clin Pharmacol</i> , 46:203-206, 1998.
	C36	Spannagl <i>et al.</i> , "A fast photometric assay for the determination of hirudin," <i>Haemostasis</i> , 21:36-40, 1991.
	C37	Stevens-Simon <i>et al.</i> , "Racial variation in vaginal pH among healthy sexually active adolescents," <i>Sex Transm Dis</i> , 21:168-172, 1994.
	C38	Tang <i>et al.</i> , "Genetic immunization is a simple method for eliciting an immune response," <i>Nature</i> , 356:152-154, 1992.
	C39	Taubes, "Salvation in a snippet of DNA," <i>Science</i> , 278:1711-1714, 1997.
	C40	Ulmer <i>et al.</i> , "Toward the development of DNA vaccines," <i>Curr Opin Immun</i> , 8:531-536, 1996a.
	C41	Urisu <i>et al.</i> , "Inhibitory action of amlexanox on interleukin-3-induced enhancement of histamine releasability of human leukocytes," <i>Arerugi</i> , 39(10):1448-1454, 1990. (ABSTRACT)
	C42	Yankauckas <i>et al.</i> , "Long-term anti-nucleoprotein cellular and humoral immunity is induced by intramuscular injection of plasmid DNA containing NP gene," <i>DNA Cell Biol</i> , 12:771-776, 1993.
	C43	Zuckerbraun <i>et al.</i> , "Triclosan: cytotoxicity, mode of action, and induction of apoptosis in human gingival cells in vitro," <i>Eur J Oral Sci</i> , 106:628-636, 1998.
	C44	Co-Pending US Application No. 10/072,320 filed on February 7, 2002, (NANO:002USD1).

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